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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,766	01/17/2002	Richard J. Fitzpatrick	1932.1110-001	5568

21005 7590 03/15/2006

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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 03/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/051,766

**Applicant(s)**

FITZPATRICK ET AL.

**Examiner**

Blessing M. Fubara

**Art Unit**

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-34 is/are pending in the application.
- 4a) Of the above claim(s) 9,11-19 and 25-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,8,10, 20-24, 33 and 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                                                 |                                                                                         |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                            | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>07/29/2005</u> . | 6) <input type="checkbox"/> Other: _____                                                |

### **DETAILED ACTION**

Examiner acknowledges receipt of request for request for reconsideration, remarks and IDS filed 12/09/05. No claim amendment is amended. Claims 1-5 and 7-34 are pending. Claims 9,11-19 and 25-32 are withdrawn from consideration. Claims 1-5,7,8,10, 20-24, 33 and 34 are considered.

#### ***Priority***

1. Applicants' statement regarding the Chilean application is acknowledged and the document will be purged from the electronic file wrapper by the appropriate department. Therefore, no new oath/declaration/application data sheet is required.

#### **Request for Rejoinder of claims 9, 11-19 and 30-32 with the elected claims**

The claims are not rejoined because the elected claims are not found allowable. Applicants request to include claims 25-29 is persuasive and examination will be extended to claims 25-29 upon allowance of claim 1.

#### ***Claim Rejections - 35 USC § 103***

2. Claims 1-5,7,8,10, 20-24, 33 and 34 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. (US 4,217,429) or Mandeville, III et al. (US 6,767,549) or Klofta et al. (US 6,238,682) or Drake et al. (US 5,419,897).
3. Applicants argue that non of the cited references disclose treating oral mucositis with ionene polymer and that oral mucositis is a side effect of anti-cancer therapy. Therefore, applicants state that the claimed invention is unobvious over the cited references. Specifically, applicants refer to a Ferretti reference which discloses that chlorhexidine offers benefits in the resolution of oral mucositis while applicants show in their specification at page 3, lines 6-12 to

Art Unit: 1618

be unsuccessful in treating oral mucositis in the hamster at a concentration of 0.5% while applicants use ionene polymer to effectively reduce the “severity” of oral mucositis at low concentrations; this finding provides surprising and unexpected improvement for oral mucositis.

4. Applicants' arguments filed 11/2/09/05 have been fully considered but they are not persuasive.

The method in the claims is administration of ionene polymer. The cited prior art administer the ionene polymer. The claimed method and the claimed agent used in the administration is the same as the disclosed method and agent. The claimed ionene agent would provide the same effect as the disclosed ionene agent when each or any is administered to a target. This flows logically from the fact that “products of identical chemical composition can not have mutually exclusive properties.” A chemical composition/agent and its properties are inseparable. The effect of the agent, in this case, ionene polymer flows naturally from the inherent properties of the agent.

Applicants statement that oral mucositis is a side effect of anticancer therapy and as such the cited prior art could not be treating oral mucositis because the cited prior art use the ionene polymer against helminth infections (Drake), anti-microbial infection (Mandeville) is not persuasive because, mucositis is a type of inflammation of the mucous membrane and microbial infections causes inflammation so also does helminth infections. A modification of the cited prior art is not necessary because the method in all the cited art is the same as the claimed method of administration and the agent administered is the same in the prior art as it is in the claims. Therefore, the effect of the agent is expected to be same for the prior art and the claims. Inflammation caused by infection is inflammation and that affecting the mucous membrane is

Art Unit: 1618

mucositis. Thus administration of the ionene polymer to a target in need of treatment for mucositis caused by infection or caused as a side effect of cancer therapy is expected to affect the severity of the inflammation in both cases.

The comparison between chlorhexidine and ionene polymer is not commensurate with the scope of the claims

The rejection follows below.

Each of the references cited above discloses use of ionene polymer to treat microbial infection or helminth infection as discussed in the previous Office action.

Wagner discloses the use of ionene polymer in treating antimicrobial infection (abstract; column 1, lines 22-26; columns 2 and 3). It is known that microbial infection causes inflammation (see column 7, lines 46-50 of US 5,789,395 as a teaching reference). Mucositis is a type of inflammation.

Mandeville, III discloses treating microbial infection in a human mammal by administering therapeutically effective amount of a polymer that comprises an amino group or an ammonium group attached to the polymer backbone via an aliphatic spacer arm (abstract; column 2, lines 5-23; column 3, lines 45-67 and columns 4 and 5). Mandeville's polymer is an ionene. It is known that microbial infection causes inflammation (see column 7, lines 46-50 of US 5,789,395 as a teaching reference). Mucositis is a type of inflammation.

Klofta discloses application of a lotion that contains antimicrobial agent (abstract; column 4, lines 55-66) and ionene polymer (column 16, line 23) is listed as an antibacterial. It is

Art Unit: 1618

known that microbial infection causes inflammation (see column 7, lines 46-50 of US 5,789,395 as a teaching reference). Mucositis is a type of inflammation.

Drake discloses the administration of an ionene polymer to treat helminth infections and infection causes inflammation (abstract). It is known that microbial infection causes inflammation (see column 7, lines 46-50 of US 5,789,395 as a teaching reference). Mucositis is a type of inflammation.

None of the references discloses treating oral mucositis. But compositions comprising ionene polymers are known in the prior art for treating infections that cause inflammations/mucositis.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the ionene polymers of Wagner or Mandeville, III or Klofta or Drake to treat inflammations. One having ordinary skill in the art would have been motivated to treat infection with the expectation that the ionene polymers would be effective in treating inflammation resulting from infection as is disclosed by the prior art.

No claim is allowed.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

Art Unit: 1618

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

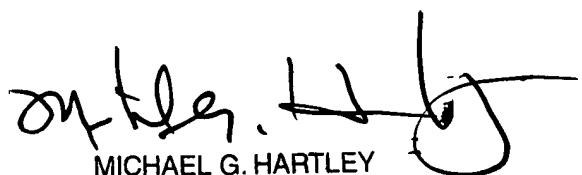
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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